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WAC	DISCUSSION DRAFT
246-102-001 **Purpose.** The purpose of cancer case reporting is to monitor the incidence of cancer in the state. Information collected through the cancer registry system is used by medical, research and public health professionals to understand, control and reduce occurrences of cancer in residents of Washington. This chapter establishes the criteria and procedures for identifying and reporting cancer cases and defines the standards for access and release of cancer information.	**246-102-001** **Purpose.** The purpose of the Washington State Cancer Registry is to monitor the incidence of cancer in the state and report applicable de-identified data in accordance with federal grant/cooperative agreement requirements. Information collected through the cancer registry system is used by research and public health professionals to understand, control and reduce occurrences of cancer in residents of Washington. This chapter establishes the criteria for identifying and reporting cancer cases. It also defines the standards for access and release of cancer case information. A brochure is available at the department providing more information about the purpose of the Washington State Cancer Registry.
246-102-010 **Definitions.** For the purposes of RCW 70.54.230, 70.54.240, 70.54.250, 70.54.260, 70.54.270, and this chapter, the following words and phrases shall have the following meaning unless the context clearly indicates otherwise: (1) "Cancer case" means: (a) Any malignant neoplasm with the exception of basal and squamous cell carcinoma of the skin; (b) All brain tumors; (c) Basal and squamous cell carcinoma of the external genital organ sites (vulva, labia, clitoris, prepuce, penis, scrotum); (d) Cancer in situ, except carcinoma in situ of the uterine cervix; or	**246-102-010** **Definitions.** The definitions in this section apply throughout this chapter unless the context clearly indicates otherwise. 1) A reportable condition means: (a) Any malignant or cancerous neoplasm with the exception of basal and squamous cell carcinoma of the skin; (b) Neoplasms noted as carcinoma in situ or non-invasive carcinomas, except carcinoma in situ of the uterine cervix; (c) All solid intracranial and central nervous system tumors, including the meninges and intracranial endocrine structures;

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(e) Other diagnoses necessary to meet the reporting requirements of the Center for Disease Control's National Program of Cancer Registries, the National Cancer Institute's Surveillance Epidemiology and End Results Program, the Commission on Cancer, and the North American Association of Central Cancer Registries (a copy is available for review at the department). (2) "Reporting entity" means any health care facility; hospital; laboratory (pathology, clinical, or reference); ambulatory surgical center; independent radiation or oncology clinic; independent imaging facility; treatment center, physician office and/or attending health care provider office that may have information on patients with reportable diagnoses. (2) "Cancer diagnosis or treatment facilities" means hospitals, surgical centers, outpatient radiation therapy centers, doctors' offices, independent clinical laboratories and any other facilities where cancer cases are diagnosed or treated. (3) "Confidential information" means any information which could lead to the identification of cancer patients, cancer diagnosis or treatment facilities, independent clinical laboratories, or attending health care providers. (4) "Contractors" means agencies designated by contract with the department of health to perform activities related to identification, collection, and processing of cancer data. (5) "Department" means the Washington state department of health. (6) "Designees" means hospital-based cancer registries and other persons or entities designated by the department to perform data collection activities. (7) "Hospital-based cancer registry" means a cancer registry which is maintained by a hospital or other health care facility. (8) "In situ" means tumors described as "in situ" by the pathologist reading the diagnostic report(s). (9) "Institutional review board" means any board, committee, or other group formally designated by an institution, or authorized under federal or state law, to	(d) Carcinoma of the external genital organ sites (i.e., vulva, labia, clitoris, prepuce, penis, scrotum); (e) All hematopoietic and lymphoid neoplasms including certain pre-malignant hematopoietic conditions; (f) Other diagnoses as required to meet the reporting requirements of the Centers for Disease Control's National Program of Cancer Registries, the National Cancer Institute's Surveillance, Epidemiology and End Results Program, and the North American Association of Central Cancer Registries. The department will publish a reportable list annually. 2) "Health Care Facility" means any facility or institution, whether public or private, proprietary or not for profit, including but not limited to hospitals, including general hospitals, free-standing radiation therapy, imaging, and oncology centers, all pathology and cytology laboratories, including hospital laboratories, health maintenance organizations and other outpatient facilities such as free-standing surgical centers, which diagnose, evaluate or provide treatment to patients with conditions that are or may be reportable to the State Cancer Registry. 3) "Health Care Provider" means any licensed physician, dentist, or other health care professional diagnosing, evaluating, or providing treatment to patients with conditions that are or may be reportable to the State Cancer Registry. 4) "Reporting entity" means any health care facility, institution or health care provider, including health care facilities or institutions with and without cancer registry staff, including but

review, approve the initiation of, or conduct periodic review of research programs to assure the protection of the rights and welfare of human research subjects as defined in RCW 70.02.010. (10) "Patient" means a case, suspected case or contact. (11) "Principal health care provider" means the attending health care provider recognized as primarily responsible for diagnosis and treatment of a patient, or in the absence of such, the health care provider initiating diagnostic testing or treatment for the patient. (12) "Reportable cancer case" means any cancer case diagnosed in a Washington state resident after the effective date of these rules. (13) "Resident" means an individual residing in Washington state at the time of cancer diagnosis. (14) "Stage of disease" means a cancer classification system encompassing attributes of a tumor as determined and described by: (a) *Summary Staging Guide, Surveillance Epidemiology and End Results (SEER), Program, April 1977*; except when superseded by more up-to-date measures (a copy is available for review at the department); and (b) *Manual for Staging of Cancer, 5th Edition, American Joint Committee on Cancer, (AJCC), 1998*, except when superseded by more up-to-date measures (a copy is available for review at the department). (15) "State cancer registry" means the statewide cancer data base maintained by the department of health. (16) "State cancer registry contract" means the legal agreement by which contractors are authorized to obtain information on reportable cancer cases. It also means the document specifying the contractors' obligations to the state cancer registry with respect to how and when information is collected, processed, and provided and how quality assurance standards are met.	not limited contracted staff, that would or potentially report case information to the State Cancer Registry. 5) "First course treatment" means all methods of treatment documented in the treatment plan after the original diagnosis and administered to the patient before disease progression or recurrence. 6) "Case finding documents" means (a) Disease and operation indices; (b) Pathology, cytology, and autopsy reports; (c) Patient radiation logs; (d) Patient chemotherapy logs; (e) Office visit logs; and (f) Other alternative documents necessary to identify and provide information on reportable cases. 7) "Case report" means a complete report documenting a diagnosis of cancer. This includes; (a) Patient demographic information; (b) Diagnostic evaluation and staging information; (c) First course treatment information; and (d) Other information necessary to meet the reporting standards of the Centers for Disease Control's National Program of Cancer Registries as provided by the State Cancer Registry annually. 8) "Certified Tumor Registrar (CTR)" means the credential

	awarded to those individuals by the National Cancer Registrars Association that pass the certification examination and meet the requirements to maintain the credential. 9) "Department" means the Washington State Department of Health. 10) "State Cancer Registry" means the Washington State Cancer Registry. 11) "Health care facilities with cancer registry staff" means those hospitals or institutions with in-house cancer registries or have contracted cancer registry staffing services. 12) "Health care facilities without cancer registry staff" means those hospitals or institutions without in-house cancer registries or contracted registry staff services. 13) "Confidential information" means any information which could lead to the identification of cancer patients, cancer diagnosis or treatment facilities, independent clinical laboratories, or attending health care providers. 14) "ICD-O-3" means International Classification of Diseases for Oncology, Third Edition, published by the World Health Organization. This is the standard reference for coding of

	histology and primary site. 15) "Stage of Disease" or "Evaluation of Disease" means how far the tumor has spread from the organ or site of origin at the time of diagnosis and treatment planning. 16) "Physician only case" means the patient is diagnosed and treated in a physician office only.
246-102-020 **Who must report.** By statute (RCW 70.54.240), the responsibility for identifying and reporting cases of cancer rests with health care facilities, independent clinical laboratories, and other principal health care providers. The department may, at its discretion, delegate some or all of these responsibilities to contractors or other designees. A list of the contractors and designees responsible for identifying and reporting cases of cancer diagnosed at specific sites in Washington is available for review at the department.	**246-102-020** **Who must report.** 1) The following will submit cancer case reports to the State Cancer Registry: (a) Reporting entities that diagnose a patient with a reportable case; (b)Reporting entities that that provide staging or evaluation services to a patient with a reportable case; and (c)Reporting entities that provide first course treatment to a patient with a reportable case. 2) In the event that a health care provider refers patients to health care facilities with cancer registry staffing for diagnostic, staging, or first course treatment services, the primary responsibility for reporting the case to the State Cancer Registry will rest with the health care facility. 3) In the event that a health care provider refers patients to health

	care facilities without cancer registry staffing for diagnostic, staging or first course treatment services, the primary responsibility for reporting the case to the State Cancer Registry will be shared by the health care provider and the health care facility. The State Cancer Registry will make every effort to avoid duplication of reporting by these entities. 4) Health care providers are responsible to submit reportable cases to the State Cancer Registry within six months of diagnosis when they are identified as physician only cases.
T 246-102-030 **Cancer case identification.** (1) Contractors or designees shall identify reportable cancer cases diagnosed and treated at cancer diagnosis and treatment facilities. (2) Cancer diagnosis or treatment facilities shall: (a) Organize case finding documents by procedure or service date to permit identification of cancer cases; and (b) Submit or make available, case finding documents including the following if maintained: (i) Disease and operation indices for cancer cases; (ii) Pathology and cytology reports; (iii) New patient radiation logs; (iv) New patient chemotherapy logs; and	**246-102-030** **Cancer case identification** 1) Reporting health care facilities and providers are responsible to conduct appropriate case finding activities to identify reportable cases. 2) The State Cancer Registry will: (a) Publish a reportable list annually. (b) Publish a recommended case finding list annually. (c) Publish a list of required data items annually.

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(v) Other alternative case finding documents that are necessary to identify or verify reportable cancer cases; (c) Cancer diagnosis or treatment facilities shall submit case finding documents by paper form, computer disk, or electronic file or make batched hard copy documents available for on-site review, within forty-five days of the date of service. (3) On request, principal health care providers shall identify to contractors, designees, or the department reportable cancer cases diagnosed at facilities other than hospitals, surgical centers, and outpatient radiation therapy centers (as specified under WAC 246-102-030 and 246-102-040) unless the patient was hospitalized for additional cancer diagnosis or treatment services within one month of diagnosis.	
246-102-040 **Data collection requirements.** (1) Contractors or designees shall complete cancer abstracts for patients identified through cancer diagnosis and treatment facilities. (2) Cancer diagnosis or treatment facilities shall provide contractors or their designees with access to pathology and cytology reports and all medical records pertaining to identified cancer cases. (3) On request by the contractor, designee or the department, principal health care providers or their staff shall be responsible for completing cancer abstracts for patients diagnosed at facilities other than hospitals, surgical centers, and outpatient radiation therapy centers, unless the patient was hospitalized for additional cancer diagnosis or treatment services within one month of diagnosis. (4) The following information items shall be included in cancer abstracts, providing the information is available from the patient's medical records: (a) Patient information: (i) Name;	**246-102-040** **Data reporting requirements.** 1) Case reports will be completed and submitted to the State Cancer Registry within six months of the date of diagnosis or date patient is first seen for the cancer if the diagnosis is made elsewhere. 2) The following must be included in case reports, providing the information is available from the patient's medical records: a) <u>Patient information:</u> (i) Name (last, first, middle) (ii) Address at time of diagnosis; (iii)Sex;

(ii) Address at time of diagnosis; (iii) Sex; (iv) Race; (v) Hispanic origin; (vi) Birthdate; (vii) Age at time of diagnosis; (viii) Social Security number; (ix) State or country of birth; (x) Usual occupation; (b) Diagnostic information: (i) Date first seen for this cancer; (ii) Primary site or sites; (iii) Histologic type or types, behavior and grade; (iv) Date of each diagnosis; (v) Method or methods of diagnostic confirmation; (vi) Stage of disease at diagnosis using: (A) Summary stage; and (B) AJCC system if maintained by the cancer diagnostic or treatment facility; (vii) Sequence;	(iv) Race(s); (v) Spanish/Hispanic origin; (vi) Birthdate; (vii) Age at time of diagnosis; (viii) Social Security number; (ix) Usual occupation; <u>(b) Diagnostic information</u>: (i)Date first seen for this cancer; (ii)Date diagnosis made; (iii)Primary site or origin of cancer (iv)Laterality (if applicable) (v) Histology type or types, behavior and grade of tumor (vi) Documentation, including dates, of pertinent diagnostic or evaluation studies, biopsies, and stage of disease at diagnoses. (vii) Text that describes the extent of disease (stage of disease) at diagnosis and documents Collaborative Staging coding used.

(viii) Laterality; (c) First course of treatment information: (i) Date of initial treatment; (ii) All treatment modalities given as part of first course of therapy; (d) Other information: (i) Name and address of cancer diagnosis or treatment facility providing information; (ii) Medical record number; (iii) Name and address of principal health care provider; and (iv) Other items necessary to meet the reporting requirements of the Center for Disease Control's National Program of Cancer Registries, the National Cancer Institute's Surveillance Epidemiology and End Results Program, the Commission on Cancer, and the North American Association of Central Cancer Registries (a copy is available at the department). (5) The department may require submission of additional information from contractors or designees as needed to assess data reliability and validity. (6) Contractors shall prepare detailed data collection protocols for inclusion in the state cancer registry contract.	(viii)Previous cancers (sequence) with primary site and year of diagnosis. <u>(c)First course of treatment information:</u> (i)Date initial treatment began or, in the absence of treatment, date decision for no treatment made. (ii)Description of all treatment given as part of the first course (i.e., surgery, radiation, chemotherapy, BRM/immunotherapy, hormone, or other therapies). In the absence of treatment, a statement as to why no treatment was given. <u>(d)Other information:</u> (i) Date of last contact. (ii)Vital Status at time of last contact. (iii)Identification of reporting entity providing information (name, address, or National Provider Identification number. (iv) Health care providers involved with case (National Provider Identification numbers). (v)Other items necessary to meet the reporting requirements of the State Cancer Registry as provided annually.
246-102-050 **Form, frequency, and format for reporting.** (1) Contractors or designees shall: (a) Prepare electronic data files containing information from cancer abstracts	**246-102-050** **Form, frequency, and format for reporting.** 1) Case reports will be prepared and submitted in a format specified by the State Cancer Registry.

in a format specified by the department; and (b) Provide electronic files to the state cancer registry at intervals specified by written agreement with the department. (2) On request by the contractor, designee or the department, principal health care providers shall complete and submit cancer abstracts to contractors, designees, or the department under WAC 246-102-020 and 246-102-030 within sixty days following a patient's cancer diagnosis date if the patient was not hospitalized for a cancer-related diagnosis or treatment within one month of diagnosis.	2) Case reports will be completed and submitted to the State Cancer Registry within six months of diagnosis or date patient is first seen for the cancer if the diagnosis is made elsewhere. 3) All pathology laboratories, including those at health care facilities and institutions, will provide; (a) Copies of pathology documents with reportable or potentially reportable cases within fifteen days of the close of each month; (b) Updated information made to the pathology report such as addendums and amendments; and (c) Patient demographic information will be included in submissions.
246-102-060 **Data quality assurance.** (1) Contractors or designees shall: (a) Assess the completeness and accuracy of case identification and data collection through computerized edit programs and on-site audits, or make available information and documentation for this purpose; and (b) Maintain a system for retrieval of completed cancer abstracts for a period up to ten years. (2) Cancer diagnosis or treatment facilities shall: (a) Make available to the contractor, designee or the department, all case finding source documents and medical records for data quality assurance activities. (b) Maintain a system for retrieval of case finding source documents and	**246-102-060** **Data quality assurance.** 1) The State Cancer Registry is responsible to insure the overall quality assurance of all cases received and to insure that national guidelines are applied to case information. 2) The State Cancer Registry will follow-up with health care facilities or providers for additional case information as needed to insure completeness and quality of case reporting. 3) The State Cancer Registry is responsible to provide relevant education and training related to reporting cases or potential cases. 4)In order to insure complete and accurate case reporting the State

medical records for a period up to ten years. (3) The department may require contractors or designees to make available all findings from data quality assurance activities for review and verification.	Cancer Registry shall: a) Offer education and training opportunities to Certified Tumor Registrars on staff at health care facilities or institutions. b) Offer education and training opportunities to individuals who do not have the Certified Tumor Registrar certification. c) Provide technical assistance and expertise to reporting entities throughout the state. 5) The State Cancer Registry will perform audits of reporting entities to insure accurate and complete reporting. The State Cancer Registry will provide thirty days notice of an audit.
246-102-070 **Access and release of information.** (1) Cancer registry information shall be used only for statistical, scientific, medical research and public health purposes. Contractors and designees must comply with chapter 70.02 RCW regarding the disclosure of patient health care information. (2) The department may release confidential registry information for research purposes after the research project has been reviewed and approved by an institutional review board and a confidentiality agreement is negotiated (a copy of the institutional review board procedures and application are available from the department). (3) The department may release confidential registry information for projects to assess threats to public health or improve public health practice after the project has been reviewed and approved by the department and a data-sharing agreement is negotiated (a copy of the procedures for data-sharing agreements is available from the department).	**246-102-070** **Access and release of information.** 1) State Cancer registry information will be used only for statistical, scientific, medical research and public health purposes. 2)The department may release confidential registry information for: a) Research purposes after the research project has been reviewed and approved by the Washington State Institutional Review Board. b) Projects to assess threats to public health or improve public health practice after the project has been reviewed and approved by the department and a data-sharing agreement is in place. (3) The State Cancer Registry will produce an Annual Report within 24

(4) Cancer diagnosis or treatment facilities may require contractors or designees to sign an agreement of confidentiality regarding access and release of cancer data and prepare, administer, and maintain confidentiality oaths as needed. (5) Cancer diagnosis or treatment facilities shall adhere to recommendations in RCW 70.54.260 regarding content of confidentiality agreement if confidentiality agreements are used. (6) Cancer diagnosis and treatment centers shall make available to cancer patients printed information which describes the purpose of the state cancer registry, the statutory requirements which apply to health care facilities, independent clinical laboratories, and other principal health care providers to identify and report cases of cancer to the state cancer registry, and to protect the confidential information that is reported, the public health and research uses of information in the state cancer registry, the circumstances under which cancer registry information is disclosed for these purposes and the relevant RCW and WAC pertaining to the state cancer registry.	months of the end of the diagnosis year that includes age-adjusted incidence rates , age-adjusted mortality rates for the diagnosis year by sex and, where applicable, by sex, race, ethnicity, and county at diagnosis. (4) The State Cancer Registry will make available to health care facilities and health care providers information for patients and their families that describes the purpose of the State Cancer Registry, the statutory requirements, uses of case information, the circumstances under which cancer registry information is disclosed, and the relevant RCW and WAC pertaining to the State Cancer Registry.

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COMMENTS?

Comments regarding this discussion draft may be made to the Department on or before January 29, 2010, using the following addresses:

http://www.doh.wa.gov/Rules/schedule.htm

CancerRegistry.Rule@doh.wa.gov

THANK YOU